Docket No.: 2002.749US (PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Cornelius Marius Timmers et al.

Application No.: 10/540,335 Conf. No.: 8737

Filed: January 10, 2006 Art Unit: 1623

For: TETRAHYDROQUINOLINE DERIVATIVES Examiner: Layla Bland

AND THEIR USE AS FSH RECEPTOR

MODULATORS

Examiner: Layla Bland

## REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT DETERMINATION UNDER 37 CFR §1.705(B)

Commissioner for Patents

P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

In response to the Notice of Allowability issued August 14, 2009, Applicants respectfully request reconsideration of the Patent Term Adjustment of  $\underline{0}$  days noted on page 3 of the Notice, and request that it be corrected to  $\underline{80}$  days. The present request, being filed along with the issue fee transmittal, is timely, 37 C.F.R. \$1.705(b).

The office is authorized to charge deposit account no. 50-4205 the required fees set forth in 37 C.F.R. §1.18(e) (\$200) and 37 C.F.R. §1.705(b)(1).

Applicants respectfully submit that the correct Patent Term Adjustment is <u>80</u> days. The basis upon which Applicants request reconsideration of the patent term adjustment is as follows (for details see attached AIPA Term Calculation Report utilizing Professor Kayton's patent Term® on line program):

Petition for Reconsideration of Patent Term Adjustment

 Under the 14-Month Rule [(\$1.703(a)] the present application was filed on January 10. 2006 and the First Action was mailed May 2, 2007. Accordingly under the 14-Month Rule the period of adjustment for the USPTO delay is 53 days which is also reflected in the Patent Term Adjustment History.

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- Under the 3-Month Rule [(§1.704(b)], a period of adjustment of 17 days of Applicant delay has been calculated from the Final Action mailed February 20, 2008 to the date of Reply to this Action, i.e., the Notice of Appeal mailed June 6, 2008, as is also reflected in the Patent Term Adjustment History.
- Under the 3-Month Rule [(§1.704(b)], a period of adjustment of 60 days of Applicant delay has been calculated from the Non-Final Action mailed December 5, 2008 to the date of Reply to this Action, May 4, 2009, as is also reflected in the Patent Term Adjustment History.
- 4. However, should a patent issue after June 20, 2008 (three years from the June 20, 2005 date of commencement under 35 U.S.C. §371(b) in an international application), adjustment of the patent term pursuant to 35 U.S.C. \$154 (b)(1)(B) [(\$1.703(b), stipulating issuance of a patent within three years of the application filing datel would be implicated based upon the Wyeth et al. v. Dudas ruling recently published (No. 07-1492 D.D.C. September 30, 2008). Assuming an estimated issue date of February 23, 2010, it is respectfully submitted that the period of adjustment for USPTO delay (in accordance with the ruling in Wyeth et al. v. Dudas) begin on the day after the three year period, June 20, 2008 (see attached AIPA Term Calculation Report utilizing Professor Kayton's patent Term® on line program) and end on the aforementioned estimated issue date, which is a period of adjustment due to USPTO delay of 104 days. In addition, with respect to the three-year rule, it is noted that the Notice of Appeal mailed June 6, 2008 was considered to be withdrawn in view of the Request for Continued Examination mailed October 3, 2008. Accordingly, it was believed that the exclusion rule pertaining to appellate review [(37 C.F.R. 1.703(b)(4)] was not applicable.

5. Accordingly, Applicants respectfully submit that the patent term adjustment period is the total days debited the USPTO, 157 days, minus the total number of days debited Applicants, 77 days, to yield a total patent term adjustment of 80 days ((see attached AIPA Term Calculation Report utilizing Professor Kayton's Patent Term on line program).

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The present application is not subject to a terminal disclaimer [37 C.F.R. §1.705(b)(2)(iii)].

Applicants reserve the right, under 37 C.F.R. §1.705(d), to request further revisions to the patent term adjustment, should the Office fail to note the revised patent term adjustment on the face of any patent issuing from the present application, or fail to timely issue any patent issuing from the present application.

Early and favorable action is earnestly solicited.

Dated: November 12, 2009

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Attachment 104451 1.DOC Respectfully submitted,

By Juan Res

Susan Hess

Registration No.: 37,350 Attorney For Applicant(s)



## AIPA Term Calculation Report

|                     | APPLICATION  | APPLICATION INFORMATION |                                    |
|---------------------|--|-------------------------|------------------------------------|
| Docket Number:      | 2002.749US   | User Name:              | Hess, Susan                        |
| Application Number: | 10/540,335   | Firm/Company Name:      | Organon, a part of Schering-Plough |
| Filing Date:        | 12/16/2003   | User Comments:          |                                    |
| Title/Inventor(s):  | TETRAHYDORQUINOLINE DERIVATIVES AND THEIR USE AS FSH RECEPTOR MODULATORS; Cornelis Marius Timmers, Oss, (NL) | Calculation Generated:  | 11/10/2009 04:46:00 PM ET          |

| AIPA  | AIPA TERM CALCULATION SUMMARY |
|---|-------------------------------|
| Earliest Referenced Application under 35 USC § 120, 121, or 365(c): | 12/16/2003                    |
| International Filing Date:  | 12 / 16 / 2003                |
| Net Adjustment Credits:   | 157 Days                      |
| Net Adjustment Debits:  | 77 Days                       |
| Patent Term Adjustment:   | 80 Days                       |
| AIPA Patent Term End Date:  | 03 / 05 / 2024 (1)            |
|   |                               |

(1) Assumes payment of all maintenance fees, no intervening acts, and no 35 USC 156 regulatory extensions. Terminal disclanner(s) filed in this case, if any, may result in an earlier term and date. Without adjustment, the term would end on 12/16/2023.

| COMF<br>(H                         | ARISON TO USPTO PAIR PTA TAB (2) Based on PAIR Data from (1/10/2009) |                  |            |
|------------------------------------|--|------------------|------------|
|                                    | PAIR PTA Tab   | Your Calculation | Comparison |
| Credit Days (USPTO Delay):         | 53   | 157              | ×          |
| Debit Days (Applicant Delay):      | 77   | 77               | Match      |
| Total Patent Term Adjustment Days: | 0  | 80               | ×          |
|                                    |  |                  |            |

(2) Comparison is shown for USPTO Delay, Applicant Delay, and Total Patent Term Adjustment fields displayed on USPTO PAIR Patent Term Adjustments (PTA) tab on 11/10/2009. See the full PAIR PTA tab, tite wrapper (e.g., Notice of Allowance, PTA-related petitions), and issued patent for complete information on USPTO calculated PTA.

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|---|--|---|-----------------------|
| 01/10/2006<br>Application Fulfilled<br>Requirements of 35<br>USC 371  | 12/20/2005<br>Notice of DO/HO<br>Missing<br>Requirements   | 06/20/2005<br>National Stage<br>Commenced under 35<br>USC 371(b) or (f)   | Event                 |
| 14-Month PTO First Action  1970 must mail a notification under 35 USC 132 or a notice of allowance under 35 USC 113 or faire than 14 months after the date on which the application was filled under 35 USC 11(a) or failfield the requirements of 35 USC 37 (a) or after the international application. Period of adjustment (oredit) begins on the day after the date that is 14 months after the date on which the application was filled under 35 USC 11(a) or failfield the requirements of 35 USC 37 and ending on the date of malting of either an action under 35 USC 132 or a notice of allowance under 35 USC 151(a) whichever occurs first. 35 USC 154(b)(1)(A)(i); 37 CFR 1.702(a)(1), 1.702(a)(1). | 2-Month Applicant Response to Notice or Action  Period of adjustment (credits) shall be reduced for the period in excess of 3 months taken to rely to any PTO notice or action making any rejection, objection, augment, or other protest, beginning on the day after the date in the 33 months after the date in the system of the Office communication and ending on the date in the date in the system of the Office communication and ending on the date in the date in the state of the state of the office of the office communication and ending on the date in the system of the office of the Office communication and ending on the date in the system of the office of th | 2-Year PTO Issue of Patent PTO must issue a patent within 3 years (not including exclusions) after the date on which the application was filed undex 30 USC 111(a) or the autional stage commenced under 3 USC 211(b) or (f) in an international application. Period of adjustment (credies) begins on the day after the clate that it 3 years after the date on which the application was filed undex 50 USC 111(b) or (f) in an international application and earling on the date on patent was itsued but not including the sum of the listed declationary periods. 35 USC 154(b)(10/B; 37 CFR 1.702(b), 1.702(b), 1.703(b). You have elected to analyze this rule without applying the USPTO 37 CFR § 1.703(f). Actual Deby similation in decremanting Credit Days under this rule. This is consistent with DC District Court ruthing in Wyoth et al. v. Dudas, No. 07-1492 (D.D.C. September 9), 2.008). | Rule Invoked          |
| First PTO Action:<br>05/02/2007<br>Non-final Action   | Applicant Response: 01/10/2006 Onther Declaration Filed (Original or Supplemental)   | Issue Date:<br>02/23/2010<br>Issue Date   | Related Event         |
|   |  |   | Exclusion<br>Days (4) |
|   | 0  |   | Debit<br>Days (5)     |
| ន   |  | 104   | Credit<br>Days (6)    |

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| 12/11/2007<br>Reply after Non-final<br>Action under 37 CFR   | 09/11/2007<br>Non-final Action   | 08/01/2007<br>Reply after Non-final<br>Action under 37 CFR  | 05/02/2007<br>Non-final Action  |
| 4-Month PTO Response to Applicant Reply.  PTO must respond to a reply under 25 USC 132 not later than 4 months after the date on which the reply was filed. The period of adjustment (rectails) begins on the day after the date that is 4 months after the date a reply under 37 CFR 1.11 or in compliance with 37 CFR 1.113(c) was filed and cading on the mailing date of other an action under 35 USC 132, or a review of allowance under 35 USC 135, whichever occurs first 35 USC 135(b)(1)(A)(ii), 37 CFR 1.702(a)(2), 7.705(a)(2), 30 CFR 1.702(a)(2), 7.705(a)(2), 30 CFR 1.702(a)(2), 30 CFR 1.7 | 2-Month Applicant Response to Nutice or Action Period of adjustment (credits) shall be reduced for the period in excess of 3 months nature to rely to any PTO notice or action making any releation, objection, argument, or other request, beginning on the day face the date that a favorable of the date that a favorable of the date from the standard of the release of the date from the control of the date from the control of the date from the control of the date from the standard of the date from the standard of the date o | 4-Month PTO Response to Applicant Reply.  PTO must reappoid to a reply under 25 USC 132 not later than 4 months after the date on which the reply was filed. The period of adjustment (notifies) begains on the day after the date they was filed there date a reply under 37 UTP, 1411 or in compliance with 37 C FR 1, 113(s) was filed and ording on the malting date of other an action ordinates a replace of all bottom counted 35 USC 152, or a revitee of all bottom counted 35 USC 151, whichever occurs first. 35 USC 154(b)(1)(A)(d); 37 C FR 1.702(a)(2), 7.703(a)(2),37. | 3-Month Applicant Response to Notice or Action  Period of adjustment (credits) shall be reduced for the period in excess of 3 months taken to reply to any PTO notice or action making any rejection, objection, argument, or other request, beginning on the day fifter the date that is 3 months after the date of rationing or transmission of the Office communication and ending on the date the reply was filed. The period, or shortened stantony period, for reply set in the action or motice has no effect on this deadline. 35 USC 154 (b)(2)C(Xii); 37 CFR 1.704(b).  Where applicant shows, in spite of all of early applicant was unable to respond within the 3-month period all or part of the care, applicant was made to the control of the control of the care applicant shows, in spite of all or part of the care. |
| PTO Response:<br>02/20/2008<br>Final Rejection   | Applicant Response: 121/1207 Reply After Non-final Action under 37 CFR   | PTO Response: 09/11/2007 Non-final Action   | Applicant Response: 08/01/2007 Reply Afer Non-final Action under 37 CFR   |
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| 05/04/2009<br>Reply after Non-final<br>Action under 37 CFR   | 12/05/2008<br>Non-final Action   | 10/03/2008<br>Request for<br>Continued<br>Examination under 35<br>U.S.C. 132(b)  | 02/20/2008<br>Final Rejection  |
| 4-Month PTO Response to Applicant Reply.  PTO must respond to a reply under 35 USC 132 not later than 4 months after the date on which the reply was filed. The period of adjustment (credits) begins on the day after the date fat set months after the date of the UT of the Compliance with 37 CFR 1.113 (o) was filed and ending on the making date of either an action under 35 USC 154 or notice of allowance made: 35 USC 15. whichever occurs first. 35 USC 154(b)(1)(A)(fi); 57 CFR 1.702(a)(2), 1.703(a)(2),3. | 2-Month Applicant Response to Nutice ar Action Period of adjustment (credits) shall be reduced for the period in excess of 3 months taken to reply to any PTO notice or action making any rejection, adjection, against, or other queues, beginning on the day fine to date the rate of a months after the date for rapid was filed. The period, or adstructed schalincy partially for early on the date the rapy was filed. The period, or adstructed schalincy partial, for rapy of the action or notice has no effect on this deadline. 35 USC 154 (b)(2)(C)(t)); 37 CFR 1.704(b). Where applicant shows, in spite of all date care, applicant was made to respond within the 3-month period, all or part or adjustment up the enistated for up to 3 additional months. 35 USC 154(b)(2)(C); 37 CFR 1.705(c). | Exclusion for Continued Examination  3. Year PTO Issue Requirement does not include the period consumed by continued examination of the application under 35 USC 133(b), beginning on the downwhich a request for continued examination of the application under 35 USC 135(b) was fled and conding on the date the patient was issued. 35 USC 154(b) (1)(3)(b); 37 CFR I. 70.35(b)(1), 7.705(b)(1). | 3-Month Applicant Response to Notice or Action  Period of adjustment (credits) shall be reduced for the period in excess of 3 months taken to reply to any PrO notice or extent making any rejection, objection, augment, or other request, beginning on the day after the date that is 3 months after the date of mailing or transmission of the Office communication and ording on the date the reply was filed. The period or shortened stantory period for reply set in the action or motic has no effect on this deadline. 35 USC 154 (b)(2)(C)(ii);  37 CFR 1.704(b).  Where applicant shows, it aspite of all of accere, applicant was unable to respond within the 3-month period, all or part of a factore, applicant shows the period, all or part of a faither than the period of the per |
| PTO Response:<br>08/14/2009<br>Notice of Allowance<br>under 35 USC 151   | Applicant Response: 65(042000 Reply After Non-final Action under 37 CFR  | Issue Date: 02/23/2010 Issue Date  | Applicant Response: 06/06/2008 Notice of Appeal to Board of Patent Appeal and Interferences  |
|  |  | 509  |  |
|  | 60   |  | 17   |
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| 80  |    |     |  | t Days (8):  | Patent Term Adjustment Days (8):                             |
|-----|----|-----|--|--|--|
| 157 | 77 | 509 |  | nd Credit Days:  | Net Exclusion, Debit, and Credit Days:                       |
| 0   | 0  | 0   |  |  | Overlap Days (7):  |
| 157 | 77 | 509 |  | and Credit Days:   | Total Exclusion, Debit, and Credit Days:                     |
|     |    |     | Issue Pate:<br>02/23/2010<br>Issue Date                                    | 4-Month PTO Issue of Patent  PTO must issue a patent not later than 4 months after the date on which the issue few was paid under 35 USC 151 and all outstanding requirements were satisfied. If the period of adjustment (results) begins on the day after the date that is 4 months 151 after the date the issue fee was paid and all outstanding requirements were satisfied and ends on the day the patent issues. 35 USC 154(b)(1)(A)(iv), 37 CFR 1.702(a)(4), 1.703(a)(6).   | 11/14/2009<br>NI Issue Fee Payment<br>under 35 USC 151       |
|     | •  |     | Applicant Response:<br>11/14/2009<br>Issue Fee Psyment<br>under 35 USC 151 | 2-Month Applicant Response to Notice or Action  Period of adjustment (certity) shall be reduced for the period in excess (37 nonths taken to reply to any PTO notice or extent making any ejection, objection, augment or obtaining and the date of mailing any produced or the state of the period, or all the object of the date that is 3 nonths at the date of mailing and the date of the period, or all the Office of estatutory period, for reply as filed. The period, or all state of statutory period, for reply set in the nation or notice has no effect on this deadline. 35 UNC 154 (n)(2)(C)(b);  37 CFR, 17.04(b), 37 UNC 154 (n)(2)(C)(b);  Where applicant shows, in spite of all date care, applicant was unable to respond within the 3-month period, all or part of adjustment may be cristated for up to 3 additional months. 35 UNC 154 (n)(2)(C), 37, 37 UNC 17.05(c)  You have indicated that no 1.705(c) Showing of Due Care was made. | 08/14/2009  08/14/2009  Notice of Allowance under 35 USC 151 |

The patent professional using this system is responsible for reviewing and updating the Apply Term Rules tab to ensure all data is complete, correct, and consistent with their (3) Calculations of Debit, Credit, and Exclusion Days are determined by the rule assignments, assignments of related events, and analysis options in the Apply Term Rules tab.

jndgment and interpretation of applicable legal authority.

(4) Exclusion Days are periods which are not included in elemining the end of the 3-year period after the clue on which the application was field under 35 USC 11(4), or the national stage communicated target varieties of the property of the property of the property of the 3-Year PTO Issue of Patent rule. See 35 USC 154(b)(1)(9)(0)(4)(ii), 37 CFR 1.702(b)(1)(5), 1703(b)(1)(4).

(5) Debit Days are days where grounds for reduction of period of adjustment of patent term exist. See, e.g., 37 CFR 1.704. Debit Days are sometimes referred to as Applicant

(7) To the extent credit periods overlap other credit periods, debit periods overlap other debit periods, or exclusion periods overlap other exclusion periods, overlaps are subtracted so that each eatendar day generates at most one credit (ay, one debit day, and one exclusion day. (8) Patent Term Adjustment Days equals Net Credit Days minus Net Debit Days, but is not less than zero (6) Credit Days are days where grounds for adjustment of patent term exist. Sec. e.g., 37 CFR 1.702, 1.703. Credit Days are sometimes referred to as USPTO Delay.